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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,829	12/26/2006	Martin Dugas	22328-US	5668

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EXAMINER	
MYERS, CARLA J	

ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,829	DUGAS ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-27* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-10, and 14-16 (in part), drawn to methods for distinguishing immunologically defined subtypes by assaying for the level of a nucleic acid marker.

Group II, claims 1-16 (in part), drawn to methods for distinguishing immunologically defined subtypes by assaying for the level of a polypeptide marker.

Group III, claims 17 and 18 (in part), drawn to the use of a nucleic acid marker to manufacture a diagnostic.

Group IV, claims 17 and 18 (in part), drawn to the use of a protein marker to manufacture a diagnostic.

Group V, claims 19-21 (in part), drawn to a kit comprising a nucleic acid marker.

Group VI, claims 19-21 (in part), drawn to a kit comprising a polypeptide marker.

Group VII, claims 22-27 (in part), drawn to a reference data bank containing information regarding the level of a nucleic acid (i.e., a nucleic acid expression profile).

Group VIII, claims 22-27 (in part), drawn to a reference data bank containing information regarding the level of a polypeptide (i.e., a polypeptide expression profile).

2. The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

A 371 case is considered to have unity of invention only when there is a technical relationship among those inventions involving one or more of the same or corresponding technical features. The expression "special technical feature" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. In the instant application, the claims are linked by the technical feature of markers associated with immunologically defined genotypes. However, such markers and methods of using markers for distinguishing immunologically defined genotypes were known in the art at the time the invention was made. For example, Kohlmann (Genes, Chromosomes & Cancer. April 2003. 37: 396-405; cited in the IDS) discloses methods for distinguishing precursor B-ALL subtypes from precursor T-ALL subtypes using the expression of the ADA marker (Table 3, page 404). Note that the marker ADA is disclosed in present Table 1.6 for the same purpose. Tsutsumi (Cancer Research. 2001. 63: 4882-4887; cited in the IDS) also discloses methods for distinguishing ALL subtypes using the markers CD44 and ME1S1. Note that the CD44 and ME1S1 markers are disclosed in present Table 1.6 for the same purpose. Additionally, regarding Group V and VI, kits comprising nucleic acid probes and polypeptide probes for detecting markers were known in the prior art at the time the invention was made. For example, the commercially available Affymetrix U133 microarray comprises nucleic acid probes that can be used to distinguish immunologically defined ALL subtypes. Thus, there is no special technical feature linking the recited groups, as would be necessary to fulfill the requirement for unity of invention.

Further restriction requirement applicable to Groups I-VIII

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

The sequences and combinations of sequences set forth in Table 1.1, 1.2, 1.3, 1.4, 1.5, 1.6, 2.1, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9, 2.10, 2.11, 2.12, 2.13, 2.14 and 2.15 AND the different subtypes recited in claim 1 (e.g., methods which distinguish ball from all other subtypes; methods which distinguish cpre from all other subtypes etc) and in claims 17, 19 and 22 (i.e., ALL subtypes Pro-B-ALL, c-ALL, Pre-B-ALL, c-ALL/Pre-B-ALL, mature B-ALL, precursor B-ALL, Pro-T-ALL, Pre-T-ALL, cortical T-ALL, mature T-ALL, and T-ALL).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. That is, Applicant is required to elect one polynucleotide or one polypeptide or one particular combination of polynucleotides or polypeptides. Applicant is also required to elect one or one particular combination of the ALL subtypes recited in the claims. The election of the polynucleotide or polypeptide must be commensurate with the election of the ALL subtype. The election should identify the particular affymetrix id number of the elected polynucleotide or polypeptide. For example, if Applicant elects Group I, Applicant may further elect Affymetrix ID 201029 (#1 in Table 1.1) and a method for distinguishing ball from all other subtypes or Applicant may elect Affymetrix ID 201029 (#1 in Table 1.1)

and 203373 (#2 in Table 1.1) and methods for distinguishing ball from all other subtypes, or methods for detecting Affymetrix ID 218351 (#1 in Table 1.2) and methods for distinguishing cpre from all other subtypes.

The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Each of the recited species are encompassed by claims 1-27.

The following claim(s) are generic: No claims are generic.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the recited ALL subtypes differ from one another with respect to their causes and attributes and each ALL subtype has a different expression pattern associated there with. Further, each of the recited nucleic acids differ from one another with respect to their nucleotide structure and the proteins that they encode. The nucleic acids recited in Tables 1 and 2 thereby have a different chemical structure and different biological activity. Similarly, each of the polypeptides has a different amino acid sequence, a different binding

specificity and a different functional activity. Thus, the claimed nucleic acids and polypeptides do not have both a "common property or activity" and a common structure as would be required to show that the inventions are "of a similar nature."

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.
In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)-272-0735.

The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

/Carla Myers/
Primary Examiner, Art Unit 1634